K072167

SEP - 6 2007

ADVANCED VASCULAR DYNAMICS
A Semler Technologies Company

510(k) Summary

Herbert J. Semler
31 July 2007

Trade name - ComfortPress™ Vascular Compression Assist Handle
Common name - femoral access compression device
Classification name - Clamp, Vascular (21 CFR 870.4450 DXC)
Predicate device - Compass™ Compression Assist Handle (K053398)

This device handle is similar to the Compass handle, but of a different shape. The ComfortPress device provides an alternative to the use of mechanical clamping systems or direct hand holding pressure to obtain hemostasis following femoral vascular catheterization procedures. The ComfortPress handle mates with the SuperComfort™ Disc, one of which is provided with each handle.

The device is provided as sterile, with a SuperComfort disc attached. The handle with the disc is manually positioned at the femoral vascular access site. The medical practitioner then applies holding force sufficient to obtain hemostasis.

Use of the handle and disc by a medical practitioner avoids prolonged direct contact with bodily fluids, and alleviates bio-mechanical stress which may occur during traditional direct digital compression of the femoral artery post-cardiac catheterization.

The ComfortPress Compression Assist Handle with the SuperComfort™ Disc is intended for use during and following femoral vascular catheterization procedures to assist in obtaining and maintaining hemostasis.

The handle and disc provide a mechanical means for a medical practitioner to hold external pressure at or near the site of femoral vascular access. Direct pressure is used to obtain and maintain hemostasis on the access site or at a pressure point.

Market testing determined that the use of a handle and disc for holding manual pressure, rather than use of fingers directly on the access site, was more comfortable and less stressful to the care giver.

Testing was conducted to determine that the ComfortPress device provides mechanical fit to the CompressAR® SuperComfort™ Disc and may be used to apply pressure. It was concluded that the ComfortPress Compression Assist Handle, used with the SuperComfort™ Disc, is equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2007

Advanced Vascular Dynamics Division
Mr. Gary Mills
2326 N.W. Everett St.
Portland OR 97210

Re: K072167
Trade/Device Name: ComfortPress Vascular Compression Assist Handle
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: July 31, 2007
Received: August 6, 2007

Dear Mr. Mills:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072167

Device Name: ComfortPress™ Vascular Compression Assist Device

Indications for Use:

This device is indicated for use to provide hemostasis of the femoral vascular access site during and following catheterization or cannulation procedures.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072167